O. PREMARKET NOTIFICATION [510(K)] SUMMARY

This summary document is being submitted in accordance with section 807.92(c).

The submitter of the 510(k) is:

Mark O'Donnell
Section Supervisor, Regulatory Affairs
Allergan, Inc.
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Date Summary Prepared: November 22, 20000

Device Subject to this 510(k):

Trade Name: MOJAVE Cataract Extraction System

Common Name: Phacofragmentation or Phacoemulsification System

Classification Name: Phacofragmentation System (886.4670)

Comparison with Predicate Devices:

The MOJAVE Cataract Extraction System device that is the subject of this 510(k) is substantially equivalent to the predicate device, the SOVEREIGN® Cataract Extraction System (K981116).

The significant differences between the MOJAVE Cataract Extraction System and the predicate device, the SOVEREIGN® Cataract Extraction System (510(k) K981116) are listed below:

- There are structural differences, externally, internally and to the user interface.
- There is different host software, a new operating system and redesigned printed circuit boards.

Device Description:

The MOJAVE Cataract Extraction System is a phacoemulsification system that is used by ophthalmic surgeons during cataract surgery. Accessories, which are connected to the console, aid the surgeon in breaking up and removing the cataract from the patient's eye. The MOJAVE Cataract Extraction System is substantially equivalent to the predicate device listed above.

Indications for Use:

The MOJAVE Cataract Extraction System is an AC-powered device with a fragmenting needle intended for use in cataract surgery to disrupt a cataract with ultrasound and extract the cataract.

Brief summary of non-clinical tests and results:

Performance testing was conducted on the MOJAVE Cataract Extraction System. Performance in an *in vivo* model system was comparable to the predicate with respect to phacoemulsification, irrigation/aspiration, diathermy, vitrectomy and fluidics.

The results of these tests indicate that MOJAVE performs equivalently to the predicate device. The overall function and intended use of the modified device are substantially equivalent to the predicate device. Therefore, the MOJAVE is substantially equivalent to the predicate device in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2001

Mr. Mark O'Donnell
Section Supervisor, Regulatory Affairs
Allergan, Inc.
2525 Dupont Ave.
Irvine, CA 92713-9534

Re: K003638
Trade Name: MOJAVE Cataract Extraction System
Regulatory Class: II
Product Code: 86 HQC
Regulation: 886.4670
Dated: November 22, 2000
Received: November 24, 2000

Dear Mr. O'Donnell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): *Unknown at this time* – K003638

Device Name: MOJAVE Cataract Extraction System

Indications for Use:

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PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-the-Counter Use _____
(per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003638